October 29, 2020

KARL STORZ Endoscopy-America, Inc
Winkie Wong
Regulatory Affairs Manager
2151 E. Grand Avenue
EI Segundo, CA 90245

Re: K202957
Trade/Device Name: Flexible Video Cysto-Urethroscope (C-view)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ, FBO
Dated: September 29, 2020
Received: September 30, 2020

Dear Winkie Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Mark Antonino
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202957

Device Name
Flexible Video Cysto-Urethroscope (C-view)

Indications for Use *(Describe)*
The Flexible Video Cysto-Urethroscope C-VIEW is used to provide visualization and operative access during diagnostic and therapeutic endoscopic procedures of urinary tract including the urethra, bladder, ureters, and kidneys.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:	KARL STORZ Endoscopy-America, Inc 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Winkie Wong Regulatory Affairs Manager 310-658-3427 (phone)
Date of Preparation:	October 20th, 2020
Type of 510(k) Submission:	Special
Device Identification:	Trade Name: Flexible Video Cysto-Urethroscope (C-view) Common Name: Cystoscope and accessories, Flexible/Rigid (FAJ) Cystourethroscope (FBO)
Product Code:	FAJ, FBO
Classification Number and Name:	21 CFR 876.1500 (Endoscope and Accessories)
Predicate Device(s):	Flexible HD Cysto-Urethroscope (K191357) – Primary Flexible CMOS-Video-Cysto-Urethroscope (K131364) – Secondary ***The above predicate devices have not been subject to any recall***
Device Description:	The Flexible Video Cysto-Urethroscope C-VIEW (Part Number: 11272VUE) is intended to be used with multiple compatible CCUs: C-MAC (8403ZX, cleared via K182186) and C-HUB II (20290301, cleared via K182186). Identical to the predicates, the scope cannot be operated on its own because it is a videoscope

<table>
<tr><td></td><td>whose image data output is provided in the form of video signals and sent to the CCU for decoding and display. Therefore, when the scope is connected to the compatible CCUs, it becomes the Flexible Video Cysto-Urethroscope C-VIEW System, which provides visualization and operative access in the urinary tract.</td></tr>
<tr><td>Indications for use:</td><td>The Flexible Video Cysto-Urethroscope C-VIEW is used to provide visualization and operative access during diagnostic and therapeutic endoscopic procedures of urinary tract including the urethra, bladder, ureters, and kidneys.

The indications for use are identical to the primary predicate device. The subject device includes kidneys when compared to the secondary predicate. This difference does not have different intended use because the kidney is part of the urinary tract.</td></tr>
<tr><td>Technological Characteristics:</td><td>The subject device is a modification of the primary predicate, 11272VHU, cleared via K182723 and most recently via K191357 for the addition of HLD for reprocessing. It is also the next generation of the secondary predicate device, 11272VU, cleared via K131364 as lower cost alternative imaging systems when compared to the primary predicate.

The comparison of technological characteristics is as follow:
<table>
<tr><th></th><th>Subject Device

Flexible Video Cysto-Urethroscope System</th><th>Primary Predicate K191357

Flexible HD Cysto-Urethroscope System</th><th>Secondary Predicate K131364

Flexible CMOS Video Cysto Uretheroscope</th></tr>
<tr><td>Type of scope</td><td>Flexible</td><td>Same as the subject device</td><td>Same as the subject device</td></tr>
<tr><td>Insertion Shaft Diameter</td><td>5.2 mm</td><td>5.5 mm</td><td>5.5 mm</td></tr>
<tr><td>Insertion Shaft Length</td><td>37 cm</td><td>Same as the subject device</td><td>Same as the subject device</td></tr>
<tr><td>Working Channel Diameter</td><td>2.3 mm</td><td>2.3 mm</td><td>2.2 mm</td></tr>
<tr><td>Suction Port/Channel</td><td>Via working channel</td><td>Yes</td><td>Via working channel</td></tr>
<tr><td>(Deflection (°)</td><td>Up: 210^0

Down: 140^0</td><td>Same as the subject device</td><td>Same as the subject device</td></tr>
<tr><td>(C1) Type of Imager</td><td>CMOS</td><td>CMOS</td><td>CMOS</td></tr>
<tr><td>(C2) Field of View</td><td>100°</td><td>Same as the subject device</td><td>Same as the subject device</td></tr>
<tr><td>(C3) Direction of View</td><td>0°</td><td>Same as the subject device</td><td>Same as the subject device</td></tr>
<tr><td>(C4) Depth of Field</td><td>5-50 mm</td><td>Same as the subject device</td><td>Same as the subject device</td></tr>
<tr><td>(C5) On-axis Resolution (minimal)</td><td>1.8 lp/mm @ 5 mm
16 lp/mm @50 mm</td><td>2.5 lp/mm @3 mm
40 lp /mm@50 mm</td><td>1.1 lp/mm @ 5 mm
11 lp/mm @ 50mm</td></tr>
</table>
</td></tr>
</table>

	(C6) Light Source	Internal LED	Same as the subject device	Same as the subject device
	(C7) Compatible CCUs	C-MAC (8403ZX) C-HUB II (P/N20290301)	IMAGE1 S	C-MAC (8402ZX)

Non-Clinical
 	
Performance Data:
	There are no performance standards or special controls developed under Section 514 of the FD&C Act for endoscopes. However, the subject device follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance:
	
	• Electrical Safety and EMC
	  ○ IEC 60601-1
	  ○ IEC 60601-1-2
	  ○ IEC 60601-2-18
	  ○ IEC 62471
	  ○ ISO 10993
	  ○ ISO 8600
	• FDA Guidance Document
	  ○ Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
	• Optical Performance Testing
	  ○ Color Reproduction and Color Contrast
	  ○ Illumination Detection Uniformity
	  ○ Spatial Resolution & Depth of Field
	  ○ Latency
	  ○ Distortion
	  ○ Signal-to-Noise Ratio (SNR) & Sensitivity
	
	Additional bench testing was performed to ensure the device met its design specifications. The bench testing performed verified and validated that the Flexible Video Cysto-Urethroscope (C-view) has met all its design specification and is substantially equivalent to its predicate devices.			

Substantial Equivalence:	The indications for use, operating principles, technological characteristics and features are similar, if not identical, between that subject device and the predicate devices, Flexible HD Cysto-Ureteroscope (K191357) and CMOS Flexible Video Endoscope (K131364). The minor difference between the subject and predicate devices that does not raise new or different questions or safety and effectiveness are listed above in Technological Characteristics section. As proven by the comparisons, the differences do not raise different questions of safety and effectiveness because the intended use, operating principles,			

	technological characteristics, and features are similar, if not identical. Both systems also comply with identical standards and safety testing, where applicable. Substantial equivalence on the effectiveness of the subject device is supported by the comparison of the images and standard image quality characteristics including, but not limited to the performance testing listed above.
Clinical Performance Data:	Clinical performance is not required to demonstrate substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to establish substantial equivalence.
Conclusion:	The Flexible Video Cysto-Urethroscope C-VIEW is substantially equivalent to its predicate device. The non-clinical bench and comparative testing demonstrate that the device is as safe and effective as the legally marketed devices.